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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,434	04/16/2004	Joseph Levy	LEVY=18A	9886
1444 7590 01/30/2009 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER SHEIKH, HUMERA N	
			ART UNIT	PAPER NUMBER
			1615	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/825,434

Applicant(s)

LEVY ET AL.

Examiner

Humera N. Sheikh

Art Unit

1615

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8, 9, 11, 12, 14, 15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 8, 9, 11, 12, 14, 15, 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/799,251.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

Receipt of the Response, Amendment and Applicant's Arguments/Remarks, all filed 10/29/08 is acknowledged.

Applicant has overcome the following rejection by virtue of persuasive remarks: (1) The 35 U.S.C. §103(a) rejection of claims 7, 10, 13 and 16 over Schlipalius (US '790) in view of Gorbach (US '631) or Gaynor et al. (US '924) has been withdrawn.

Claims 1-6, 8, 9, 11, 12, 14, 15, 17 and 18-22 are pending in this action. New claims 19-22 have been added. Claims 7, 10, 13 and 16 have been cancelled. Claims 1-6, 8, 9, 11, 12, 14, 15, 17 and 18 have previously been withdrawn (non-elected invention). Claims 19-22 have been examined in this action and stand rejected.

* * * * *

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson *et al.* (hereafter "Jackson") (U.S. Pat. No. 5,807,586) in view of Schlipalius (U.S. Pat. No. 6,132,790).

Jackson ('586) teaches a dietary supplement composition and method for supplementing the dietary needs of a women comprising once daily administration of a composition comprising a physiologically effective amount of phytoestrogens in combination with mixed carotenoids,

such as lycopene (see reference column 1, lines 4-10); (col. 4, line 39 – col. 5, line 14); (col. 6, line 63 – col. 7, line 25) and Table 1 at column 10.

The dietary supplements are formulated to reduce the risk factors of disease, such as iron deficiency anemia, high cholesterol and CHD, osteoporosis and some cancers during the various life stages of a woman (col. 7, lines 25-35).

The dietary supplements may be formulated as a tablet, capsule, powder, gel or liquid, or dietary bar and are preferably formulated for once daily administration (col. 3, lines 22-26). The phytoestrogens may be administered at levels of less than 25 mg per day (col. 5, lines 6-14).

With regards to the amount of carotenoid claimed, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Jackson teaches the concept of providing a dietary supplement composition having a combination of phytoestrogens with mixed carotenoids. Jackson, as noted above, teaches that carotenoids can be included in the composition, of which lycopene is included. Lycopene has been shown to provide for beneficial effects and lycopene intake, for example, has been inversely associated with the risk of (cervical) cancer. See col. 7, lines 4-9. Jackson does not teach a mixture of lycopene, phytoene and phytofluene.

Schlipalius (*790) teaches a carotenoid composition comprising carotenoids, such as lycopene, phytoene, phytofluene and mixtures thereof (see col. 3, lines 10-19). The carotenoid composition is derived from natural resources to result in a natural carotenoid composition (col. 1, lines 10-13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a mixture of carotenoids, such as a mixture of lycopene, phytoene and phytofluene as taught by Schlipalius within the formulations of Jackson. One would do so with a reasonable expectation of success because Schlipalius teaches such a dietary formulation mixture of carotenoids (*i.e.*, lycopene, phytoene and phytofluene), which are known to provide beneficial antioxidant activity and reduce the risk factors of various diseases, such as heart disease and cancer. The expected result would be an effective method for supplementing the dietary needs of women to result in reduced adverse effects.

* * * * *

Pertinent Art

▪ **DeMichele *et al.* (U.S. Patent No. 6,013,665):**

DeMichele *et al.* teach methods for enhancing absorption of lipophilic compounds whereby compositions are provided that include phytoestrogens and carotenoids, such as lycopene (see column 7, lines 41-61).

Response to Arguments

Applicant's arguments filed 29 October 2008 have been fully considered and were found to be partially persuasive.

- **35 U.S.C. §103(a) rejection over Jackson et al. (US '586) in view of Schlupalius (US '790):**

Applicant argued, "Jackson teaches simultaneous administration of many different active ingredients. The present composition substantially contains no active ingredients other than the phytoestrogen(s) and carotenoid(s)."

This argument was not persuasive. It is noted that Jackson teaches the inclusion of additional ingredients such as vitamins, minerals and elements besides from the phytoestrogens and carotenoids disclosed in the reference. Applicant desires that their composition be "substantially free of any other active component". This limitation does not distinguish over the art of record because it cannot be seen as to how the additional ingredients (i.e., vitamins/minerals) in combination with the phytoestrogens and carotenoids of Jackson would be detrimental or adversary if added to the formulation of the instant invention. Moreover, the claim language presented does not exclude the additional ingredients of Jackson, which are merely vitamins and minerals and supplemental elements. Furthermore, the instant composition utilizes open-ended "comprising" claim language which would permit the additional vitamins and minerals of Jackson. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising," the

terms containing ' and mixture' are open-ended.")). The additional ingredients disclosed by Jackson would only appear to further enhance their formulation and process, rather than provide for negative effects. Language has not been presented that would limit the instant composition solely to the phytoestrogen(s) and carotenoid(s) desired by Applicant.

Applicant argued, "The method claimed herein is to reduce undesirable effects of hormone replacement therapy (HRT) while simultaneously providing positive effects of HRT, while Jackson discloses a method for dietary supplementation during different life stages of a woman."

This argument was not deemed convincing. The method claimed is vague in terms of what the "undesirable effects" actually are as well as what specific "positive effects" Applicant is referring to. While it is noted that Jackson discloses that their composition is effective as a means to supplement dietary needs in a woman during various life stages, the composition of Jackson, nonetheless, does comprise the same components, namely the phytoestrogens in combination with carotenoid(s). Hence, the composition of Jackson would also be able to function as a means of reducing any "undesirable effects" while simultaneously providing "positive effects", based on their teaching of the same ingredients, absent a showing of evidence to the contrary.

Applicant argued, "Jackson does not teach the use of one or more carotenoids for the purpose of reducing undesirable effects inherent in HRT."

This argument has been considered but was not persuasive. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to

achieve the same advantage or result discovered by applicant. >See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

Applicant argued, "As described in paragraph 39 of the present application, the method claimed herein is limited to co-administration of phytoestrogens with one or more carotenoids of the type which do *not* have substantial vitamin A activity. The carotenoids of the present method are non-provitamin A carotenoids, unlike those disclosed in Jackson."

This argument was not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., carotenoids devoid of provitamin A activity) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argued, "Although Jackson discloses the possibility of using non-provitamin A carotenoids, such as lycopene and lutein, no details concerning the required doses of these carotenoids or serum levels achieved are provided."

This was not deemed convincing since the determination of suitable amounts is within the level of one skilled in the art, obtained through routine or manipulative experimentation, to obtain optimal results, as these are indeed variable parameters attainable within the art. Moreover, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine

experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). Furthermore, no unexpected or superior results have been observed in the instant amounts claimed. The prior art clearly teaches a similar formulation having similar ingredients as that desired by Applicants.

Applicant argued "Schlipalius adds nothing to Jackson and has nothing to do with ameliorating effects of HRT."

The Examiner was not persuaded by this argument. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the secondary reference of Schlipalius amply resolves the deficiency of Jackson and was relied upon for the teaching that it is well known in the art to employ a combination of or a mixture of carotenoids. Schlipalius vividly teaches a carotenoid composition comprising the same carotenoids claimed by Applicant - namely, lycopene, phytoene and phytofluene and mixtures thereof (see col. 3, lines 10-19 of Schlipalius). Hence, Schlipalius is sufficient for all that it suggests and teaches.

Next, Applicant argued, "High concentrations of lycopene (such as 5 micromolar) result in a very high level of inhibition of phytoestrogen-induced cell proliferation."

Applicant's arguments have been considered but were not persuasive since Applicant's arguments do not establish the scope of claims being presented. The claims are silent in terms of any reference to inhibition of cell proliferation and are also silent regarding avoidance the

development of cancerous conditions. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argued, "Jackson is silent regarding a synergistic effect (of the combination of lycopene and phytoene as shown in Fig. 6 of the present application)."

This was not rendered persuasive. Jackson explicitly teaches the combination of phytoestrogens in combination with carotenoids, *i.e.*, lycopene. Thus, since the reference vividly teaches the use of the same components, it would be reasonable expected by one of ordinary skill in the art that the same beneficial effects (*i.e.*, synergistic effects) would also be obtained by the prior art, based on incorporation of the same components.

Applicant argued, "Schlipalius adds nothing to Jackson and provides no teaching for the specific synergistic effect of the specific carotenoid composition claimed herein."

This was not found persuasive because Schlipalius expressly teaches a carotenoid composition comprising the same carotenoids claimed by Applicant - namely, lycopene, phytoene and phytofluene and mixtures thereof and thus would also provide for beneficial results, absent a showing of evidence to the contrary.

- **35 U.S.C. §103(a) rejection over Schlipalius (US '790) in view of Gorbach (US '631) or Gaynor et al. (US '924):**

Applicant's arguments relating to this rejection have been considered and were found persuasive. Accordingly, this rejection has been withdrawn.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

This application contains claims 1-6, 8, 9, 11, 12, 14, 15, 17 and 18 drawn to an invention nonelected with traverse in the reply filed on 01/23/08. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

January 28, 2009

